

DATE OUT: May 9, 1995

SUBJECT: PRODUCT CHEMISTRY REVIEW OF an EP
DP BARCODE No.: D208774 File Symbol No.: 10182-GIL
PRODUCT NAME: Promexal X 50 Preservative

TO: Marion Johnson, PM #31
Antimicrobial Program Brnach
Registration Division (7505C)

FROM: Treva C. Alston, Chemist *Treva C. Alston*
Product Chemistry Review Section
Registration Support Branch
Registration Division (7505W)

THRU: Harold Podall, Section Head *HP 5/18/95*
Product Chemistry Review Section
Registration Support Branch
Registration Division (7505W)

SUMMARY OF FINDINGS:

This submission is for the registration of an end use product for use as an industrial preservative. This is an integrated formulation. Data for the Technical Grade Active Ingredient was submitted in the registration package. Product chemistry requirements for Series 61, 62, & 63 of the Pesticide Assessment Guidelines have been fulfilled. However, before this product may be registered, data must be submitted to the Agency for an inert used in the formulation in order to determine if it is approved for use. (See Confidential Appendix for this discussion).

PRODUCT CHEMISTRY REVIEW OF an EP

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1. Reviewer: Treva C. Alston 2. Company: Zeneca, Inc.
3. Type of Submission: Registration ☒ Reregistration ☐ New
☒ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____

4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
- Non-integrated formulation system..... ☐
 - Are all technical grade active ingredients used registered?
 • yes ☐ • no ☐, If no, specify _____
 - Integrated formulation system..... ☒
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
 • yes ☐ • no ☐ • Some are cleared, others are not ☐
 Cleared under list: • c ☐ • d ☐ • e ☐
 Are there any limitations for use as an inert under 40CFR§180.1001?
 • yes ☐ • no ☐, If yes, specify _____
- 6(b) Formulation intended for non-food use:
 • yes ☒ • no ☐ • Some are cleared, others are not ☒
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).

• yes ☒ • no ☐ • Some are cleared, others are not ☐
 If yes, the entire formulation is cleared under 21CFR\$_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7, 63-12, and 63-15, respectively: • yes ☒ • no ☐
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
2-Methyl-4,5-trimethylene-4-isothiazolin-3-one	5.0	5.25	4.75

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
 • yes ☒ • no ☐
10. The certified limits are within the standard limits as per 40CFR\$158.175 or are adequately explained if different:
 • yes ☒ • no ☐

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes ☒ • no ☐
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
 • yes ☐ • no ☐ • not applicable ☒
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
 • yes ☒ • no ☐

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

14. <u>Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1 Chemical Identity	Y	432250-01
61-2 Starting Materials & Manufact or Formulation Process	Y	432250-01
61-3 Discussion of Impurities	Y	432250-01
62-1 Preliminary Analysis	Y	432250-01
62-2 Certified Limits	Y	431387-01
62-3 Enforcement Analytical Method	Y	432250-01

15. <u>Physical/Chemical Properties</u>	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
63-3 Physical State	Y	Liquid	431387-01
63-7 Density/Bulk Density	Y	1.02	431387-01
63-12 pH of Product	Y	4.3	431387-01
63-14 Oxid/Red Action	NA		
63-15a Flammability-Flash Point (°F or °C)	NA		
63-15b Flame Extension	NA		
63-16 Explodability	NA		
63-17 Storage Stability	Y	Stable	431387-01
63-18 Viscosity	Y	1.444X10 ₋₃	431387-01
63-19 Miscibility (With Hydrocarbon solvents)	NA		
63-20 Corrosion Characteristics	Y	None	431387-01

63-21 Dielectric Breakdown Voltage	NA		
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Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Note to Reviewers: Refer to the instructions for the proper description, e. g., 63-3: emulsifiable concentrate.

CONFIDENTIAL APPENDIX A

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Reviewer: Treva C. Alston Company: Zeneca, Inc.

For the inert, [REDACTED] the registrant must provide the identity of all components, the percentage composition, CAS Registry Numbers and a Material Safety Data Sheet. The technical health and safety data sheet provided in the submission does not fulfill this requirement. Since this is proprietary information, the registrant may request the supplier of this inert to contact EPA directly referencing the File Symbol of the EPA Registration Number in the response.

Inert ingredient information may be entitled to confidential treatment